UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,143	01/12/2001	Jiangchun Xu	210121.427C23	2429

500 7590 10/08/2002

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,143	Applicant(s) XU ET AL.	
	Examiner Shubo "Joe" Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because of the following reasons. Firstly, many of those sequences are not identified by a sequence identifier ("SEQ ID NO:X") such as the sequences in Figs 8, 9, and elsewhere. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier must be used, either in the drawing or in the Brief Description of the Drawings. Secondly, these sequences that are not identified by a sequence identifier are not listed in the Sequence Listing. Thirdly, there are blanks in the specification where a sequence identifier is supposed to be present, such as pages 13, 14, 74, 79-81, and elsewhere. A new paper copy and computer readable form of the amended Sequence Listing, as well as a statement under 37 CFR 1.821(f) are required. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements will

result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Restriction/Election Requirement

Restriction to one of the following groups of inventions is required under 35 U.S.C. § 121:

1. Claims 1, 3-4, drawn to polynucleotides, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66, and claim 11 (in part), drawn to compositions comprising the polynucleotide.
2. Claim 2, drawn to isolated polypeptide, classified in class 530, subclass 330, and claim 11 (in part), drawn to compositions comprising the polypeptide.
3. Claims 5 and16, drawn to an antibody or fragment thereof, classified in class 530, subclass 388.1, and claims 11 (in part), drawn to compositions comprising the antibodies, classified in class 435, subclass 810.
4. Claim 7, drawn to a fusion protein, classified in class 530, subclass 330, and claim 11 (in part), drawn to composition comprising the fusion protein.
5. Claims 8 and 15, drawn to short oligonucleotides capable of hybridizing to polynucleotide of Group I, classified in class 536, subclass 23.1, and diagnostic kit containing said short oligonucleotides, classified in class 435, subclass 810.
6. Claim 10, drawn to T cell population, classified in class 435, subclass 325, and claim 11 (in part), drawn to compositions comprising the T cell population.

7. Claim 11, drawn to a pharmaceutical comprision comprising antigen-presenting cells, classified in class 435, subclass 325.
8. Claim 6, drawn to method of detecting the presence of a cancer using the polypeptide of group 2, classified in class 435, subclass 7.1.
9. Claim 12, in part, drawn to a method of stimulating an immune response in a patient comprising using the polynucleotide composition of group 1, classified in class 514, subclass 44.
10. Claim 12, in part, drawn to a method of stimulating an immune response in a patient comprising using the polypeptide composition of group 2, classified in class 514, subclass 02.
11. Claim 12, in part, drawn to a method of stimulating an immune response in a patient comprising using the antibody composition of group 3, classified in class 514, subclass 44.
12. Claim 12, in part, drawn to a method of stimulating an immune response in a patient comprising using the fusion protein composition of group 4, classified in class 514, subclass 44.
13. Claim 12, in part, drawn to a method of stimulating an immune response in a patient comprising using the T cell composition of group 6, classified in class 435, subclass 325.
14. Claim 12, in part, drawn to a method of stimulating an immune response in a patient comprising using the composition of antigen presenting cells of group 7, classified in class 435, subclass 325.
15. Claim 13, in part, drawn to a method of treating cancer in a patient comprising using the polynucleotide composition of group 1, classified in class 514, subclass 44.

16. Claim 13, in part, drawn to a method of treating cancer in a patient comprising using the polypeptide composition of group 2, classified in class 514, subclass 02.

17. Claim 13, in part, drawn to a method of treating cancer in a patient comprising using the antibody composition of group 3, classified in class 514, subclass 44.

18. Claim 13, in part, drawn to a method of treating cancer in a patient comprising using the fusion protein composition of group 4, classified in class 514, subclass 44.

19. Claim 13, in part, drawn to a method of treating cancer in a patient comprising using the T cell composition of group 6, classified in class 435, subclass 325.

20. Claim 13, in part, drawn to a method of treating cancer in a patient comprising using the composition of antigen presenting cells of group 7, classified in class 435, subclass 325.

21. Claim 14, drawn to a method of determining the presence of a cancer using the oligonucleotides of group 5, classified in classified in class 514, subclass 44.

22. Claim 17, in part, drawn to a method of inhibiting the development of cancer in a patient comprising using T cells and the polynucleotide composition of group 1, classified in class 514, subclass 44.

23. Claim 17, in part, drawn to a method of inhibiting the development of cancer in a patient comprising using T cells and the polypeptide composition of group 2, classified in class 514, subclass 02.

24. Claim 17, in part, drawn to a method of inhibiting the development of cancer in a patient comprising using T cells and the antigen presenting cells of group 7, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-7 are drawn to independent and/or patentably distinct products because each of these products possesses different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use, and have different functions. Additionally, these different groups do not share a common structure which elicits a common activity. The examination of the Groups will require different searches of the US Patents and scientific literature and would require consideration of different patentability issues.

Groups (1 and 5), Groups (2 and 4), and Group 3 are drawn to independent/distinct inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups (1 and 5), the critical feature is nucleic acids; for Group (2 and 4), the critical feature is a polypeptide; for Group 3, the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups (2 and 4) to be directed as to its synthesis by a polynucleotide of Groups (1 and 3), however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody support the undue search burden if they were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately.

While Groups 1 and 5 are both drawn to nucleic acids, they are directed to nucleic acids having different length; there is no common core structure for the nucleic acids as claimed. The inventions are drawn to independent and/or patentably distinct polynucleotides since each would be expected to possess distinctly different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or

use. Accordingly, a reference teaching, e.g., a 40-mer oligonucleotide would not teach/suggest or make obvious a polynucleotide comprising such oligonucleotide. Therefore, each group requires non co-extensive sequence and literature searches.

Groups 2 and 4 are drawn to polypeptides which do not have common core structure as claimed. Majority of the polynucleotides recited in claims 1, 2 are not associated with much narrower genus of peptides of Group 2. Until products of specific SEQ ID Nos. are elected, it is burdensome to establish such association between polypeptides claimed in claims 2 and claim 7.

Inventions of groups (2 and 4) and group 3 are separate and distinct as the polypeptides of Invention of groups 2 and 4 are structurally and biochemically different than the antibodies of Invention of group 3. While the antibodies may bind to the polypeptides of groups 2 and 4, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

The methods of Groups 8-24 are separate inventions because they differ in the method objectives, and/or method steps and parameters, and/or in the reagents used, and/or produce different results.

Inventions of groups 1-7 and inventions of groups 8-24 are related as products and respective processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

The inventions of Group 1 and groups (9, 15 and 22) are related as product and distinct processes of use. The polynucleotides of Group 1 can be used in the process of the invention of Group 9, which is directed to stimulating an immune response in a patient. Alternatively, the polynucleotides of Group 1 can be used for treating cancer in a patient as in claim 15, or inhibiting the development of cancer in a patient as in claim 22 , which are clearly distinct usage of such polynucleotides.

The inventions of Group 2 and groups (8, 10, 16, and 23) are related as product and distinct processes of use. The polypeptides of Group 2 can be used in the process of the invention of Group 8, which is directed to detecting the presence of a cancer, or stimulating an immune response in a patient as in claim 10. Alternatively, the polypeptides of Group 2 can be used for treating cancer in a patient as in claim 16, or inhibiting the development of cancer in a patient as in claim 23 , which are clearly distinct usage of such polypeptides.

Similarly, the antibody of ~~group~~ group 3, the fusion protein of group 4, the oligonucleotides or group 5, the T cells of group 6 and the antigen presenting cells of group 7 all can be used, respectively, in distinct processes as set forth above: stimulating an immune response in a patient, treating cancers and inhibiting the development of cancers.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single

nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

This is NOT a species election requirement.

Examination will be restricted to only the elected sequence.

Because these inventions are independent/distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to: Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER